

REMARKS

Claims 85-110 and 112 are under consideration. Claims 1-84 and 111 have been previously canceled. With the entry of this Response, Claims 85, 94, and 103 have been amended. The support for the amendments to these claims can be found in the Specification at least at page 13 (lines 19-20), page 16 (lines 1-2), page 17 (lines 11-16), page 18 (lines 27-30), page 19 (lines 12-13 and lines 20-21), page 21 (line 34) - page 22 (line 13), page 24 (lines 24-26), page 24 (line 27) – page 25 (line 3), page 49 (line 34) – page 50 (line 4), and in Figure 3. Applicants submit that these amendments do not add new matter. Claims 85, 94, and 103 are independent claims. In view of the subsequent remarks regarding these independent claims, Applicant respectfully requests allowance of all the pending claims.

35 U.S.C. § 103(A) REJECTION

I. Claims 85-87 and 89-93

The Office Action rejected Claims 85-87 and 89-93 under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,920,396 issued to Wallace *et al.* (herein “Wallace”) in view of Ringwald *et al.* (1999) “GXD: a Gene Expression Database for the laboratory mouse,” *Nucleic Acids Research*, 27(1): 106-112) (herein “Ringwald”). Applicant respectfully traverses this rejection to the extent that the rejection applies to the claims as amended.

Under 35 U.S.C. § 103(a), the Patent Office bears the burden of establishing a *prima facie* case of obviousness. A *prima facie* case of obviousness requires: (1) that there be a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the teachings of reference or to combine the teachings of multiple references; (2) that there be a reasonable expectation of success; and (3) that the prior art reference, or references when combined, teach or suggest all of the elements of the claim. (*See, e.g.*, M.P.E.P. § 2143). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and cannot be based on Applicant’s disclosure. (*See, e.g., In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *In re Fine*, 87 F.2d 1071, 1074 (Fed. Cir. 1988)). Furthermore, rejections based on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be explicit analysis including some rational underpinning to support the legal conclusion of obviousness. (*K.S.R. Int’l Co. v. Teleflex, Inc.*, 550 U.S. 14 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed.

Cir. 2006)). If the references do not teach each and every claimed element, then a finding of obviousness fails.

Applicant respectfully submits that the present Office Action fails to meet its *prima facie* burden as the combination of Wallace and Ringwald fail to teach or suggest each and every element of currently pending independent Claim 85. Applicant appreciates the thorough search and examination conducted by the Examiner and submits that this Response addresses all issues raised by the Examiner.

A. “Functional data”

The Office Action cited paragraph Figure 4 of Ringwald for teaching “functional data.” (Office Action, page 4). The Advisory Action stated that “Ringwald teaches in Figure 4 receiving query result including their details such as strain, mutation, sex, type, age, fixation, etc. to describe functions of each molecular probe used” (Advisory Action, page 2).

Ringwald fails to teach or suggest “functional data” as currently claimed. In its entirety, the legend for Figure 4, which is titled “Expression record for *in situ* data,” reads:

On the left is a sample of query result details for RNA *in situ* hybridization data. Each entry lists the bibliographic reference, the gene whose expression was analyzed, and the molecular probe used and provides links to the respective records. The first table (from the top) gives descriptions for all the specimens used, additional ones display the detailed results obtained for each specimen. A sample result set is shown for specimen 1. Level of expression is provided if given by the author. A hypertext link to the raw image data is provided, when those data are available in the database. On the right is a sample image of the *in situ* hybridization data that corresponds to specimen 1.

Furthermore, the matching written description of Figure 4 in Ringwald states:

‘Elemental’ expression results such as the time and tissue of expression, the genetic origin of the sample, the number and sizes of detected bands, and sequence information are described together with the molecular probe, the expression assay type, and the experimental conditions used (Figs 4 and 5).

(Ringwald, page 106, column 2, paragraph 5). This is not a teaching or suggestion of “functional data.”

Applicant directs the Office’s attention to the Specification. The Specification states:

The nomenclature for such categories were derived from the expressed gene anatomy database (EGAD; <http://www.tigr.org>) and the gene ontology (<http://www.geneontology.org>) functional classification systems. For example, there can be twelve functional categories, each of which is composed of specific subcategories for a total of forty six subcategories (Fig. 3, Example 1).

(page 22, lines 1-6). In Figure 3, Applicant provides examples of “functional data” for a sequence by identifying 12 different functional categories and subcategories within each broader functional category. These 12 functional categories are (i) cell defense, (ii) cytoskeletal/structural, (iii) general metabolism, (iv) mitochondria, (v) protein metabolism, (vi) secretory pathways, (vii) cell-cell communication, (viii) DNA replication/modification, (ix) intracellular signaling, (x) no match, (xi) RNA metabolism, and (xii) unknown function. The Specification further explains that each sequence is placed into one or more putative functional categories. Thus, the Specification teaches both the identity of the sequence and a putative *in vivo* function for the sequence.

Unlike Applicant’s Specification, Figure 4 in Ringwald is silent with respect to such “functional data.” Figure 4 shows (1) the gene whose expression was analyzed and (2) the molecular probe used to study the expression of that gene. However, the identification of the molecular probe used to study the expression of a gene is not a teaching or suggestion of “functional data.” Rather, as known to one skilled in the art, a molecular probe is a single-stranded DNA molecule that is used in laboratory experiments to detect the presence of a complementary sequence among a mixture of other single-stranded DNA molecules. In the art, a probe is merely a common laboratory tool. While Ringwald may identify a probe that is complementary to a specific section of a larger sequence, that probe does not provide any information regarding putative function of that sequence. Thus, the skilled person would recognize that Ringwald fails to teach or suggest “functional data.” For this reason alone, Applicant respectfully submits that the Office Action fails to meet its *prima facie* burden. Applicant respectfully requests that the Examiner withdraw this rejection and allow all pending claims.

B. “Expression Data”

In the present rejection of independent Claim 85, the Office Action stated that Wallace teaches “expression data.” (Office Action, page 3, citing Wallace, column 3, lines 24-34). Furthermore, the Advisory Action stated that “Wallace teaches receiving from a plurality of databases query result data comprising ‘sequence sets’.” (Advisory Action, page 2). The Advisory Action further stated that “this is clearly data about gene expression as claimed.” (Advisory Action, page 2).

Wallace is not a teaching or suggestion of “expression data” as currently claimed. In its entirety, the portion of Wallace cited by the Office Action reads:

Search query parameters are accepted for and search results displayed from a search request for multiple sequence sets performed against a plurality of biological data repositories in a user interface layer. The search request and the search results are processed in an intermediate layer. The user interface layer is interfaced by processing the search query parameters into a structured database query and presenting database results as the formatted search results. The structured database query is executed in a database layer. At least one queue handler loading the structured database query is provided. A plurality of biological data repositories are selected.

(column 3, lines 24-34). This is not a teaching or suggestion of any aspect of expression, which includes, but not limited to, when the sequence is expressed, where the sequence is expressed, or how robustly the sequence is expressed.

By way of background, the term “sequence sets” or “sequence data” are terms of art used to describe sequences such as a nucleotide sequence or a polypeptide sequence. A polynucleotide sequence is composed of four bases - adenine (A), cytosine (C), guanine (G), thymine (T), which are each covalently linked to a phosphodiester backbone. For example, a nucleotide sequence may be AAAGTCTGAC. A polypeptide sequence is composed of amino acids. For example, a polypeptide sequence may be PVIYNLMSKQ.

To this end, Applicant respectfully directs the Office’s attention to Figure 7 in Wallace. At the bottom of the screenshot, Wallace explains that “the lower screen area indicates the query sequence by header 127 and sequence data 128.” (column 8, lines 51-52). By entering the accession number AF30562.1 provided in item 127 into the NCBI’s “Nucleotide” database, Applicant has located the sequence 128, which is now shown below.

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1  tgtgccatgt  gctcatatta  cagacatttt  tggaaaaaatg  cattcaagtc  tcatcatgaa
61  gcatgacctt  cccagacaac  actgtgcaat  gaagcatttt  caacagtaaa  aaaaccccca
121  aaaaacctcc  tgagcattat  tcaaatataa  cagtttcagc  aaaatggaaa  atagtagcaa
181  atttgacagc  cccactaaca  tctccttggc  taaccatgac  atcgttttta  gcatgaatga
241  gtacaaagcc  atctctgttt  tccttggttt  gtttatatgt  ggcataggaa  taattggaaa
301  catcatgggtg  gttctgggtg  tgttcaccac  tcgagatatg  agaaccccaa  caaactgtta
361  cttagtttagc  ctggcagtggt  ctgatctaat  ggtcttggtta  gccgctggat  tgcccaatgt
421  atcagacagt  ttggcaggta  catggattta  tgggcatgct  ggctgcctgg  gaataactta
481  ttccagtat  ctgggaatca  acgcctcatc  atgttctatc  acagcattca  ccgtggagag
541  atacattgctg  atttgccatc  ctatgagagc  aaagactgtc  tgcactgtat  cccgggctaa
601  acgtattatt  gccattgttt  ggatcctttac  ttcaattttac  tgtatgtttt  ggttctttct
661  ggtggatatac  catgtaaaca  agagtcaaca  agttgagtgt  ggttacaagg  tctccaraaa
721  cctctacttg  ccaatctatt  tagctgactt  tgcaatatc  tacgtcacac  cactgcttgt
781  agccaccatc  ctttatggtc  tgattggtag  gattttgttc  ctcagtecca  ttccccagca
841  ccctgagagc  acaactgagc  gctggagaga  gaaaagtctc  aaagaaaaaa  acgaatcaga
901  gacagaaggc  aacaagccaa  gcaatcgtct  gaaaacaaag  ggggccctga  gctccagaaa
961  acaggtaaca  aaaatggttg  cagttgtggt  tgttttgttt  gcacttctct  ggatgcctta
1021  ccgaaccttg  gttttgggtca  actcctttat  ggacaaacct  tacctagatc  cttggttcct
1081  tcttttttgc  cgcatttgtg  tctatgccaa  cagtgccatc  aaccctgtca  tttaaacct
1141  tatgtctcag  aagttccgta  ctgccttcaa  gagactatgt  aagtgtgggc  atgaggagac
1201  ccaaagaaga  agcatgtaca  tgacaactac  aagttacagt  atggtgaaag  atggtgtcaa
1261  tactggtggg  gatactaagg  acaagccaac  tctagagaaa  acaaatataa  ttgccaaaca
1321  gaccaataaa  gcaggccctg  aaggtgatct  ctactacagt  gtcgtttaac  ttgtcaagtc
1381  tatgttatgt  gccttcatga  atatcagtgt  acctggg

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Thus, Wallace merely provides the sequence for “thyrotropin-releasing hormone receptor” gene, which is represented by a string of nucleotides (*i.e.*, A, C, G, and T). The sequence, in and of itself, fails to provide any specific information regarding the expression data of this sequence or any other sequence. Wallace fails to teach or suggest any aspect of expression, including, but not limited to, when the sequence is expressed, where the sequence is expressed, or how robustly the sequence is expressed. Thus, Wallace’s sequence data is not “expression data” as currently claimed. For this reason alone, Applicant respectfully submits that the Office Action fails to meet its *prima facie* burden. Applicant respectfully requests that the Examiner withdraw this rejection and allow all pending claims.

C. “Structural Data”

The Office Action cited Ringwald for teaching “structural data.” Specifically, the Office Action equated “structural data” with “searchable fields [that] include anatomical structure.” (Office Action, page 4, citing the figure legend for Figure 3 in Ringwald). Furthermore, the Advisory Action stated that “Ringwald teaches in Figure 4 receiving query result including their

details such as strain, mutation, sex, type, age, fixation, etc. to describe . . . structure data of the resulted specimen.” (Advisory Action, page 2).

Ringwald fails to teach or suggest “structural data” as currently claimed. In its entirety, the legend for Figure 3, which is titled “Querying gene expression data in GXD”, reads:

The left side shows the GXD Data Query Form. At the top, users can choose to sort results in a number of ways, and obtain summaries of assays (not shown) or assay results (right side). Searchable fields include gene name, gene symbol, map position, developmental stage and *anatomical structure*. *Anatomical structures* are named according to a controlled vocabulary system, which can be examined by linking on the phrase ‘browse the *Anatomical Dictionary*’. Users can specify particular assay types, select those where expression was detected, not detected, or either, and determine if *anatomical substructures* or *superstructures* should be included in the search. The sample query shown asks for all genes located within 3 cM of the *Pltr6* locus that are expressed in muscle or in a substructure of muscle. On the right is the returned assay results summary, sorted by Gene symbol. Assay IDs link to the detailed expression records. Examples of assay records are shown in Figures 4 and 5.

(emphasis added). The written description of Figure 3 in Ringwald states:

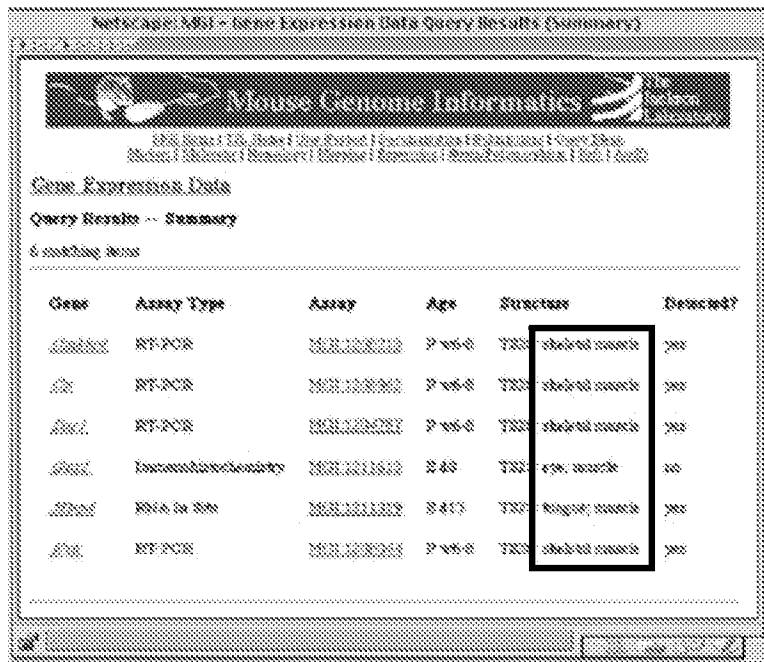
The Gene Expression Data query form . . . enables questions such as ‘In what *anatomical structures* and/or at what developmental stages are specified genes expressed/not expressed?’ and ‘What genes are expressed in/not expressed in specified tissues and/or during specified developmental stages?’. Spatial queries can take advantage of the hierarchical structure of the *anatomical dictionary* by including *anatomical substructures* or *superstructures* in the search.

(Ringwald, page 108, column 1, paragraph 2 – column 2, paragraph 1) (emphasis added).

Applicant respectfully directs the Examiner’s attention to the present Specification, which provides a discussion of structural data at least at page 13 (lines 19-20) (“3-dimensional micromolecular structures, including proteins and polynucleotides”), page 16 (lines 1-2) (“3D protein structures”), page 17 (lines 11-16) (“viewing structures in three dimensions”), and page 24 (line 27) – page 25 (line 3) (“three dimensional structure display,” “popular structure display formats,” and “popular 3D display formats”). *In vivo*, polynucleotides and polypeptides do not exist as long linear chains of nucleotides and amino acids, respectively. Rather, these molecules

adopt three-dimensional conformations. As recognized by the skilled person, Applicant's definition of structural data encompasses these three-dimensional conformations of the sequence.

Conversely, Ringwald's reference to "structure" means "anatomical structure" or "anatomical substructures or superstructures." In other words, Ringwald equates structure with an organ or a body tissue or body part. For example, in Figure 3, Ringwald identifies the following structures: skeletal muscle, eye, muscle, and tongue. (*See, e.g.*, boxed in segment below).



NetScape: MGI - Gene Expression Data Query Results (Summary)

Mouse Genome Information

Gene Expression Data

Query Results -- Summary

6 matching rows

Gene	Assay Type	Assay	Age	Structure	Detected?
Ahr1	RT-PCR	MGI123022	P w-6	skeletal muscle	yes
Ahr	RT-PCR	MGI123030	P w-6	skeletal muscle	yes
Ahr1	RT-PCR	MGI123031	P w-6	skeletal muscle	yes
Ahr1	Immunohistochemistry	MGI1211613	E 48	eye, muscle	no
Ahr1	RNA in situ	MGI1211219	E 415	tongue, muscle	yes
Ahr	RT-PCR	MGI123024	P w-6	skeletal muscle	yes

Accordingly, Ringwald's teaching of "details such as strain, mutation, sex . . . to describe . . . structure data of the resulted specimen" fails to teach or suggest a three-dimensional conformation for either a polynucleotide sequence or a polypeptide sequence. Ringwald is not a teaching of query result data comprising "structural data."

Therefore, Applicant respectfully submits that (1) Wallace does not teach or suggest "expression data," and (2) Ringwald does not teach or suggest "functional data" or "structural data." In light of Wallace's deficiencies and Ringwald's failure to cure these deficiencies, the combination of Wallace and Ringwald fails to teach or suggest each and every element of Applicant's currently pending independent Claim 85. For this reason alone, Applicant respectfully submits that the Office Action fails to meet its *prima facie* burden. Applicant respectfully requests that the Examiner withdraw this rejection and allow all pending claims.

D. “Executive Summary”

The Office Action also cited Wallace for teaching step (g) of Applicant’s currently pending Claim 85, which currently recites “displaying an executive summary of the record.” The Office Action stated that “FIG. 6 is a screenshot 100 showing, by way of example, a Web page for displaying a search summary. [Column 8, lines 35-45].” (Office Action, page 7). Furthermore, the Advisory Action stated:

the claimed language does not mention the executive summary of the record must contain ‘immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data’, hence, such claimed ‘executive summary’ is merely a brief summary of a search query. Wallace discloses such a summary in Figure 6.

(Advisory Action, page 2). Neither Figure 6 in Wallace nor Wallace’s description of Figure 6 (column 8, lines 35-45) teaches or suggests an executive summary of the record comprising the query result data comprising immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data as currently claimed.

Applicant’s disclosure explains that the “various modules can be viewed in an executive summary” and that “an ‘executive summary’ is a summary of all the information associated with a record (unique identification record),” and that “the executive summary displays the information found in the individual modules associated with the given record.” These modules include immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data. (See paragraphs [0070] and [0083] and Figure 4). Applicant’s Figure 4 shows, for example, an executive summary comprising *in situ* hybridization data and functional data.

Conversely, Figure 6 is a “search summary” that “is presented as a table listing out in columns the search name, requested user, date, sequence set, databases, and deletion flag.” (column 8, lines 36-39). In other words, Wallace teaches a listing of who conducted the search, on what day the search was conducted, what database was searched and for what sequence, what the user named the search, and whether the user wants the search to be deleted. This listing of the circumstances surrounding the search is not a teaching or suggestion of “immunohistological data,” “*in situ* hybridization data,” “functional data,” “expression data,” or “structural data.” Wallace fails to teach or suggest any information regarding putative function of a sequence, fails to provide any specific information regarding the expression data of a sequence including, but

not limited to, when the sequence is expressed, where the sequence is expressed, or how robustly the sequence is expressed, and fails to teach or suggest any three-dimensional structure for either a polynucleotide sequence or a polypeptide sequence. Consequently, Figure 6 is not a teaching or suggestion of step (g) of Applicant's currently pending Claim 85.

For at least these reasons, the combination of Wallace and Ringwald fail to provide a teaching or suggestion of Applicant's currently claimed invention. Consequently, this combination of these references fails to render as obvious Applicant's currently pending independent Claim 85. As "dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious" (*In re Fine*, 5 U.S.P.Q.2d 1569, 1600 (Fed. Cir. 1988)), the combination of Wallace and Ringwald also fails to render as obvious Claims 86-87 and 89-93, all of which depend from independent Claim 85 and incorporate every element of independent Claim 85. Applicant respectfully requests that the Examiner withdraw this rejection and allow all pending claims.

II. Claims 94-98, 100-108, 110, and 112

The Office Action rejected Claims 94-98, 100-108, 110, and 112 under 35 U.S.C. § 103(a) as obvious over Wallace in view of Ringwald, and further in view of U.S. Patent Application Publication No. 2003/0055683 to Gibson *et al.* (herein "Gibson"). Applicant respectfully traverses this rejection to the extent that the rejection applies to the claims as amended.

(i) Independent Claim 94

The Office Action applied Wallace and Ringwald in the § 103(a) rejection of independent Claim 94 in the same way and for the same disclosure for which the Office Action applied these references in the § 103(a) rejection of independent Claim 85. Here, the Office Action relied on Gibson for disclosing several steps of Applicant's currently claimed method. The Office Action stated that it would have been obvious to the skilled person to "incorporate the teaching of Gibson with the teachings of Wallace, as modified by Ringwald, for the purpose of creating update drug data for addition to the original drug information, and a transmit mechanism that transmits the update drug data to the remote device upon receiving a request from a remote device for the update drug data." (Office Action, page 10).

As discussed above, the combination of Wallace and Ringwald fails to teach or suggest receiving from the plurality of databases query result data comprising immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data, and displaying an executive summary of the record comprising such data. Specifically, the combination of Wallace and Ringwald fail to teach or suggest any information regarding putative function of a sequence, fails to provide any specific information regarding the expression data of a sequence including, but not limited to, when the sequence is expressed, where the sequence is expressed, or how robustly the sequence is expressed, and fails to teach or suggest any three-dimensional structure for either a polynucleotide sequence or a polypeptide sequence. Gibson fails to cure the deficiencies of the combination of Wallace and Ringwald. In light of these deficiencies, the combination of Wallace, Ringwald, and Gibson fails to teach or suggest each and every element of Applicant's currently pending independent Claim 94.

For at least these reasons, the combination of Wallace, Ringwald, and Gibson fail to provide a teaching or suggestion of Applicant's currently claimed invention. Consequently, this combination fails to render as obvious Applicant's currently pending independent Claim 94. As "dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious" (*In re Fine*, 5 U.S.P.Q.2d 1569, 1600 (Fed. Cir. 1988)), Applicant asserts that combination of Wallace, Ringwald, and Gibson also fails to render as obvious Claims 95-98 and 100-102, all of which depend from independent Claim 94 and incorporate every element of independent Claim 94. Applicant respectfully requests that the Examiner withdraw this rejection and allow all pending claims.

(ii) Independent Claim 103

The Office Action applied Wallace and Ringwald in the § 103(a) rejection of independent Claim 103 in the same way and for the same disclosure for which the Office Action applied these references in the § 103(a) rejection of independent Claims 85 and 94. Here, the Office Action relied on Gibson for disclosing "a query node, comprising a second memory and a second processor, wherein the second process is configured to periodically download and store a plurality of databases from an external network." (Office Action, page 14). The Office Action stated that it would have been obvious to the skilled person to "incorporate the teaching of Gibson with the teachings of Wallace, as modified by Ringwald, for the purpose of creating

update drug data for addition to the original drug information, and a transmit mechanism that transmits the update drug data to the remote device upon receiving a request from a remote device for the update drug data.” (Office Action, page 10).

As discussed above, the combination of Wallace and Ringwald fails to teach or suggest query result data comprising immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data, and fails to teach or suggest an executive summary of the record comprising such data. Specifically, the combination of Wallace and Ringwald fail to teach or suggest any information regarding putative function of a sequence, fails to provide any specific information regarding the expression data of a sequence including, but not limited to, when the sequence is expressed, where the sequence is expressed, or how robustly the sequence is expressed, and fails to teach or suggest any three-dimensional structure for either a polynucleotide sequence or a polypeptide sequence. Gibson fails to cure the deficiencies of the combination of Wallace and Ringwald. In light of these deficiencies, the combination of Wallace, Ringwald, and Gibson fails to teach or suggest each and every element of Applicant’s currently pending independent Claim 103.

For at least these reasons, the combination of Wallace, Ringwald, and Gibson fail to provide a teaching or suggestion of Applicant’s currently claimed invention. Consequently, this combination fails to render as obvious Applicant’s currently pending independent Claim 103. As “dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious” (*In re Fine*, 5 U.S.P.Q.2d 1569, 1600 (Fed. Cir. 1988)), Applicant asserts that combination of Wallace, Ringwald, and Gibson also fails to render as obvious Claims 104-108, 110, and 112, all of which depend from independent Claim 103 and incorporate every element of independent Claim 103. Applicant respectfully requests that the Examiner withdraw this rejection and allow all pending claims.

CONCLUSION

The foregoing is a complete response to the Office Action dated May 14, 2010 and the Advisory Action dated August 30, 2010. For at least the reasons provided above, Applicant respectfully requests allowance of all of the pending claims. Early and favorable consideration is solicited. If a telephone conversation would expedite the prosecution of these claims to issuance,

then Applicant's representative invites and encourages the Examiner to contact the Applicant's representative at the telephone number listed below.

With the entry of this Response, Applicant files a Request for Continued Examination, a Petition for an Extension of Time, and a credit card payment. The credit card payment is in the amount of \$960, which corresponds to the \$405 small entity fee for the Request for Continued Examination pursuant to 37 C.F.R. § 1.17(e) and the \$555 small entity fee for a three-month extension of time pursuant to 37 C.F.R. § 1.17(a)(3). Applicant submits that this is the correct amount due; however, Applicant hereby authorizes the Commission to charge to Deposit Account 14-0629 any additional fee that is required, or to credit to that same account any overpayment of fees.

Respectfully submitted,

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